eHealth Network

GUIDELINE

on

the electronic exchange of health data under
Cross-Border Directive 2011/24/EU

Laboratory Results

Release 1

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth.

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1 USE CASE DESCRIPTION

1.1 Laboratory Result Report for Cross-Border Care

This use case represents a high level of consensus on what constitutes European eHealth services, as this use case contributes to the application of patients' rights in cross-border healthcare postulated by Directive 2011/24/EU of 9 March 2011. Laboratory results are explicitly noted in Paragraph 11 c of EC Recommendation of 6.2.2019 on a European Electronic Health Record exchange format.

Use case description

Title	Laboratory Result Report sharing on a cross-border scale
Purpose	Sharing Laboratory Result Report of a patient from his country of affiliation (*Country A*) with a health professional in the country of treatment (*Country B*) and sharing Laboratory Result Report from country B to the requesting health professional and/or to another entity identified by the requesting entity. As information sharing is not limited to the cross-border use case, implementers, including Member States, could also use these guidelines for National and regional level interoperability to ensure consistency as well as avoid fragmentation and duplication of efforts.
Relevance	Many people request medical help when traveling, working or living abroad. Each individual and health professionals in Europe should have access to information about his/her medical background and history of a patient (health data) from the country of affiliation. Laboratory medicine is an essential element of the health care system. It is integral to many clinical decisions, providing physicians, nurses, and other health care providers with often pivotal information for the prevention, diagnosis, treatment, and management of disease. Ability to access patient's laboratory test results from requests submitted by all requesting entities reduces unnecessary duplicate test examinations, thus saving costs of care services as well as burden on patients. Different laboratory tests will vary in relevance, particularly regarding time of clinical validity. It is though for the receiver health professional to decide what is relevant. Benefits (both medical and economical) can be gained from increased quality of care (e.g. patient safety) and from a decrease in the effort of

	gathering/exchanging health information and provide health professionals with most up to date information to treat a patient.
Domain	Laboratory
Situation	Cross-border, (potential inter-regional or national)
Context	Clinical laboratory results play an important role in diagnosis, treatment, and follow-up of patients. Sharing of laboratory results in cross-border health information exchange is an expected and wanted further extension within the MyHealth@EU.

Furthermore, exchange of laboratory test requests and result reports will support free movement of the services as one of the key principles of the EU (Articles 56-57 of the Treaty on the Functioning of the EU).

It is important that laboratories produce high quality test results as they often are the basis for clinical decision making. Proper quality management is therefore essential.

It is also important that laboratory requests include all necessary information about specimen to enable laboratory to properly respond to the laboratory test requests, thus the requests should always include sufficient medical background information of the subject.

Laboratory area is one of the most standardised areas of the medical industry, thanks to the extended use of automation (largely used throughout the world), as well as to a long tradition in the organisation of external quality control programs. Clinical laboratories have internal quality control procedures and participate in national and/or international external quality assessment (EQA) programs.

Still, while laboratory medicine is highly standardised, comparison of results between different laboratories is a major challenge due to differences in methods, instruments, and lack of international calibrators.

Apart from supporting healthcare provision scenarios (primary use), there is an increasing need to enable secondary use of health data. Structured and standardised laboratory results are valuable data for research, innovation, policy making and regulatory activities. Thus, this interoperability effort can also contribute to the value creation in the European Health Data Space.

The Patient Summary Guidelines already provide a generic result reporting structure although this doesn't provide the necessary level of detail to support effective exchange of laboratory results report neither provides the means for |

	an exhaustive list of laboratory reports of a patient. While there are several scenarios possible in the context of cross-border exchange of laboratory results information, this guidelines will focus on the one that best fits today cross-border health information exchange paradigm. However, other scenarios are listed as an indication of further work that can be included in following versions of this guidelines.
	
	    ▪ Scenarios in scope of current version of this guidelines
	        ▪ Health professional in country B requests a Laboratory Summary based on query parameters
	        ▪ Health professional in country B requests the list of available Lab Result Reports with associated metadata and selects one
	
	    • Scenarios that can be considered in further version of this guidelines (examples):
	        o A patient goes abroad in a specialised Lab and (optionally) presents Lab order identifier, Lab professional (health professional in country B) requests Order by identifier or the list of all available Lab Orders, selects relevant Order(s), collects sample from the patient, performs the test(s) and returns the Lab Result Report to the National Infrastructure A that delivers it to the Requesting entity (similar mechanism to eP/eD mechanisms).
	        o A Lab Order is sent to a Clinical Laboratory in Country B, the patient or just the taken sample, is shipped to the same Lab, the Lab Result Report is returned to the National Infrastructure A that delivers it to the Requesting entity.
	        o The patient is abroad. He visits a Clinical Laboratory, the Lab Request is generated locally, The Lab Result Report is pushed to the destinations indicated by the Patient.

Information	Laboratory Result Report
Participants	Patient Health professional in patient's country of origin/affiliation (country A) Health professional in country of treatment (country B)
Functional process steps	**Scenario 1A: Request for Laboratory summary from Country A** 1. The patient consults a health professional in country B 2. The health professional is identified, authenticated and authorised 3. The patient is identified (identity confirmed by country A)

4. Health professional provides information to the patient on how personal health data in the Laboratory Result Report will be collected and processed.
5. Health professional in country B queries country A for a summary of the results, for example containing the latest result for every observation type or a cumulative report.
6. The Laboratory summary is electronically transferred from the patient's country of affiliation to the health professional in the country of treatment in a secure way. The health professional retrieves the Laboratory summary and uses it to provide health care service.
7. The Laboratory summary is presented to the health professional in an understandable way, namely regarding language, structure and vocabularies.

Scenario 1B: Request for Laboratory result reports from Country A

1. The patient consults a health professional in country B
2. The health professional is identified, authenticated and authorised
3. The patient is identified (identity confirmed by country A)
4. Health professional provides information to the patient on how personal health data in the Laboratory Result Report will be collected and processed.
5. Health professional in country B queries country A for a list of all lab reports of that patient.
6. Country A provides a list of laboratory result reports available for the patient and matching query parameters (for example time interval, lab specialty, study type, and test code).
7. Health professional in country B selects and requests the report from country A.
8. The Laboratory Result Report is electronically transferred from the patient's country of affiliation to the health professional in the country of treatment in a secure way. The health professional retrieves the Laboratory Result Report and uses it to provide health care service.
9. The Laboratory Result Report is presented to the health professional in an understandable way, namely regarding language, structure and vocabularies.

2 GUIDELINES FOR LABORATORY RESULT REPORT

The Member States in the eHealth Network have adopted these supplementary clauses to the eHealth Network General Guidelines for the electronic exchange of health data under Cross-Border Directive 2011/24/EU to support the exchange of Laboratory Result Report data. These guidelines add use case specific guidelines and do supplement the eHealth Network General Guidelines.

Chapter I - General Considerations

Article 1: Objectives and scope

1. These guidelines are addressed to the Member States of the European Union and apply to the implementation exchange of interoperable laboratory test result report cross-border exchange in order to support safe and efficient provisioning of care services in another Member state.
2. These guidelines could serve as a guiding principle for the national development and implementation of Laboratory Result Reports.
3. Laboratory use cases cover all types of in-vitro diagnostics performed by clinical laboratories on:
    o Human specimens (from human subject)
    o Non-human specimens paired with a human subject (for example food and house dust)

    with the exception of histopathology and medical genetics. Tests performed (analysed) by patients themselves are not covered by this document.

4. In scope - Laboratory results within the core fields of in vitro diagnostics, for example clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others.
5. Out of scope - Specialised laboratory domains that may require a specialised reporting structure: e.g. histopathology and genetics.

Article 2: Definitions

For the purpose of these guidelines, the definitions included in the Directive 2011/24/EU, in the eHealth Network General Guidelines, and the following definitions shall apply:

Term	Definition
Laboratory medicine	A clinical science and discipline, devoted to the quantitative measurement, or qualitative assessment, of any substance which can be assayed in any type of biological fluid of any animal species, thus including humans, for either medical or research purposes. The results of these measurements are translated into actionable information for improving the care and/or maintaining the wellness of both a single individual and an entire population. **Source:** Lippi, G., & Plebani, M. (2020). *CCLM*, *58*(8), 1171-1171.
Medical laboratory (also Clinical laboratory)	Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation. Note 1 to entry: These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms. *Source:* ISO 15189:2012.
Laboratory request	A request or order for a laboratory service, an intent directed from a requesting entity (request author) to a laboratory (service performer).
Laboratory result (measurement result)	The final value reported for a measured or computed quantity, after performing a measuring procedure including all subprocedures and evaluations. *Source:* PAC, 1994, *66*, 595.
Laboratory result report	A combination of specimen information and results. The report should contain information about unequivocal identification of the source and type of material analysed and the requesting agency. It may contain such other information that is pertinent to the correct interpretation of a result (e.g. confidence interval, reference data and interpretative information). *Source:* PAC, 1989, *61*, 1657.

Term	Definition
Laboratory summary	A summary created from one or many laboratory reports. The summary could include the most recent results and/or historical results for every type of observation.
Observation method (test method)	Technique used to administer a particular examination or assessment. **Source:** NCI Thesaurus.
Specimen	Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole. **Source:** ISO 15189:2012. Note: for the purposes of these guidelines, also non-biological specimen, e.g. environment specimen, are included.
Health encounter	An interaction between a patient and healthcare provider(s) for the purpose of providing healthcare service(s) or assessing the health status of a patient. ***Source: HL7 FHIR***

Article 3: Concept and intended use

1. The provisions in the eHealth Network GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU - General guidelines' apply.
2. The Laboratory Result Report should be presented to the health professional in an understandable way, namely regarding language, structure and vocabularies.
3. Implementers are encouraged to arrange for the information retrieved to be easily integrated into the Electronic medical record (EMR).
4. Exchange of laboratory results across departments and organisations will minimise need to repetition of tests and lessen burden on the patient.
5. Health insurance and payment information are included in the dataset to support any use case scenarios where this information may play an important role.

Chapter II - Legal and Regulatory Considerations

Article 4: Data protection

1. Data contained in laboratory reports are special category of personal data within the meaning of Art. 9 of the General Data Protection Regulation and therefore Member

States will need to ensure processing and storage are in line with applicable data protection requirements.

Article 5: Identification, authentication and authorisation

There being no specific additional requirements, reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 6: Patient safety

1. In addition to generic risks present in sharing of information cross-border, transmitting laboratory orders and/or reports from one context to another poses specific challenges, including lack of consensus regarding code systems for laboratory use cases in the EU. Member states should take measures to mitigate this risk, for example by building awareness of any code system mappings applied.
2. Specific risks might be identified within this use case, e.g., transcoding, unit transformation, Interpretation of ranges, relative "unfamiliarity" with methods and results, mutual recognition of test products/methods, etc.

Chapter III - Organisational and Policy Considerations

Article 7: Enablers for implementation

Laboratory is an essential domain for diagnostics and clinical decision making. Laboratory services are highly demanded by variety of practice settings and health professionals. Not all healthcare providers have their internal laboratory resources, and some tests can only be provided by specialized laboratories.

1. Access to diverse external laboratory resources is thus essential for care providers, and this access must be digitalised by means of internationally standardised ordering and reporting procedure. Member states, healthcare providers and other implementers should ensure that their implementation is in line with these guidelines and derivative specifications.
2. The ability to populate the dataset relies on a coordinated and integrated approach to laboratory information systems and patients' electronic health records. It is up to each Member State, healthcare provider or initiative to establish the necessary policies to ensure that the laboratory observations data are available.
3. Cross-border exchange of laboratory data will need robust organisational measures to ensure sustainable maintenance of common interoperability assets, i.e. code systems, concept maps, and value sets.

Article 8: Quality standards and validation

Being an essential domain for diagnostics, laboratory medicine must comply with highest standards of quality and accuracy. Still, while laboratory medicine is highly standardised, comparison of results between different laboratories is a major challenge due to differences in methods, instruments, and lack of international calibrators.

1. Whenever possible, standards should be enforced by means of regulative framework and clinical laboratories are obliged to follow certain rules and conditions.
2. External quality control schemes may be required either by law or by the accreditation entity. Field specific schemes may apply, e.g., microbiology diagnostics of specific diseases

Article 9: Education, training and awareness

1. Proper understanding and interpretation of laboratory observations depends not only on medical education and training of the recipient but also on clarity and complexity of information contained in the report and presented to the reader. That's why both clinicians as well as implementers of the data producing systems should be properly trained and aware of all aspects of laboratory work, especially on collection of samples, sample handling procedures, observations, conditions of the subject and interpretation.

2. It is also crucial to raise health professionals' awareness on the specific risks related to variability of observation results produced by different laboratories due to, e.g. use of different coding systems, methods of measurement, different calibrators, and measurement units by different laboratory service providers. Health professionals should be educated to be able to detect and cope with such variations.

Chapter IV - Semantic Considerations

Semantic interoperability is the ability of computer systems to exchange data with unambiguous, shared meaning. It is a requirement to enable machine computable logic, inferencing, knowledge discovery, and data federation between information systems. This is accomplished by adding data about the data (metadata), agreeing on shared data and information models, and linking each data element to a controlled, shared vocabulary. It is these shared data models and vocabularies, and its associated links to an ontology, which provides the foundation and capability of machine interpretation, inference, and logic.

While the journey of semantic interoperability varies across Member States, the chapters below discuss the most common elements in laboratory healthcare domain.

Article 10: Data

1. The content of the Laboratory result report Dataset is shown in section 4. The Dataset comprises a Report Header, including relevant parts of the Laboratory request, and a Report Body.
2. Laboratory result report will comprise narrative text along with coded data, the latter will allow an unambiguously way of communicating the same information between the country of affiliation and the country of treatment.
3. All clinically relevant information in coded elements must also be included and visible in a narrative part of the Laboratory Result Report.
4. It is the responsibility of the Member State to provide data in compliance with these guidelines. Member States are encouraged to align their future considerations on a national Laboratory Dataset according to the Dataset structure given in section 4.
5. For a given patient, some of the elements might be empty as no data would be applicable or available; such situations should be communicated differently.
6. The content of the Laboratory Dataset is received by the health professional in two or three languages, Country A language, English, when different from country A language and a translation to Country B language when different from English. If Country B language is unavailable for a dataset, English can be used.
7. When the available coded information in one Member State cannot be transcoded into the selected preferred code system currently, the information should, as an interim solution, be transferred encoded and/or in narrative form, in English.
8. To assure flawless interpretation, laboratory results should be recorded in a universal manner by means of standard coding systems and data models including test methods, specimens, and results.

Article 11: Terminology

1. Sharing of laboratory test results between different healthcare providers requires standardised terminology used to clearly identify the laboratory tests (such as "culture of bacteria"), examined properties (kind of property such as "mass concentration of albumin in blood plasma"), types of specimens (arterial blood, 24 hours urine collection, cerebrospinal fluid), anatomical location of sample, (e.g. sample from skin of left knee) as well as the analytes (components or elements such as Sodium, Alanine transaminase, Brucella antibody), kind of measured property (e.g., mass concentration, volume, number fraction, rate, frequency, mass etc.), results for nominal or ordinal result values, and the units by which the value is presented (for quantitative result values). As member states use different laboratory test coding systems, not only the code and a test name but also additional constituents of the test specification and result should be taken into consideration.
2. A systematic display name (Fully specified names) compiling information of the different axes of the lab test terminology has to be available, at least in English.

3. As fully specified test names are too complex for practical use in some cases, use of synonyms, for example using conventional names, for display purposes is a widely adopted practice.
4. Member States wishing to engage in cross-border communication are encouraged to use for that communication the preferred code systems as described in the Laboratory Dataset in section 4. Particularly:
    1. Quantitative result values produced by different laboratories might be expressed using different measurement units. This makes comparison of results from different laboratories difficult and may cause mistakes in result interpretation by clinicians. That is why standard test result units needs to be agreed and used for cross-border or national/regional laboratory test result exchange.
    2. Common terminology should be also specified in order to share ordinal and nominal scale result values in an understandable and interoperable way.
    3. It should be noted that additional code systems are needed for coding of specimen types, anatomic specifications, specimen collection, containers used to transfer material, processing and testing methods, devices, calibrators and laboratory test kits.

Article 12: Controlled Lists (Value set Catalogues)

1. Laboratory medicine is a rapidly evolving discipline that frequently comes up with new tests, test equipment or test methods. This will require flexible maintenance of corresponding value sets allowing cross boarder communication in the laboratory domain.
2. Relevant agreed value sets should be easily available for implementers.

Chapter V - Technical Considerations

Article 13: Technical requirements

Member States are free to choose the technical implementation of their Laboratory Dataset. Nonetheless, for cross-border exchange the format of the document for exchange shall be based on standards and profiles as agreed by the Member States for the particular technical infrastructure. The cross-border specifications are described in section 4, which also refers to supporting requirements and other relevant documentation.

Article 14: Security

Member States shall ensure that they are fully compliant with the cross-border Security Policy.

Article 15: Testing and audit

Implementers of this Laboratory result guidelines should consider testing and audit trails provisions, mainly:

1. Perform end-to-end testing with health professionals to ensure the correctness and understandability of Laboratory Report data.
2. Ensure that audit trails are recorded to support the monitoring and verification of events related with Laboratory Result information (e.g. access, transfer).
3. Demonstrate compliance with technical interoperability specifications in the scope of the implementation project.
4. Ensure proper use of all key coded elements of the result report, esp. test codes, coded result values and proper units of measurement.

3 SUPPORTING INFORMATION

This section provides supporting information and explanatory text to aid understanding of the guidelines, and the rationale behind the proposals. It therefore follows the same structure as the eHealth Network General Guidelines. This chapter can be taken as inspiration for any initiative aiming at implementing interoperable laboratory result reports.

The main goal of this chapter is to disseminate common practices for initiatives implementing the exchange of laboratory result reports.

The material in this chapter has built on work from the X-eHealth project.

Chapter I - General Considerations

Article 1: Objectives and scope

These guidelines were prepared on the basis of X-eHealth project internal deliverable ID5.3 Laboratory Requests and Reports guideline and functional specifications and represent a subset of its functional scope. The dataset described in the chapter 4 represent a non-exhaustive core set of data that can be further expanded in case of additional communication needs in a specific areas of laboratory medicine, e.g. histopathology.

Article 2: Definitions

There is no specific support information.

Article 3: Concept and intended use

These guidelines are non-binding and Member States are considered to have the right to choose freely their way of implementing Laboratory Datasets. The Laboratory guidelines focus on the content issues and the description of possible ways to produce this content for cross-border exchange, taking existing national implementations into consideration.

Implementers are encouraged to allow import of lab result information from Laboratory result reports for cross-border exchange into their EHR systems/solutions. This means that laboratory data will be not only presented to the authorized end-user by a CDA viewer, but might be stored in his/her EHR system as part of the patient's documentation.

Chapter II - Legal and Regulatory Considerations

Article 4: Data protection

There is no specific support information.

Article 5: Identification, authentication and authorisation

There is no specific support information.

Article 6: Patient safety

There is no specific support information.

Chapter III - Organisational and Policy Considerations

Article 7: Enablers for implementation

There is no specific support information.

Article 8: Quality standards and validation

Laboratory result reports might be preliminary or final but in all cases should be validated by authorised professional. Lab reports might include information about national or international accreditation of the laboratory for a particular set of tests.

Article 9: Education, training and awareness

There is no specific support information.

Chapter IV - Semantic Considerations

Article 10: Data

As laboratory test results might be produced using different measurement units and with significantly different report layouts by different laboratories, it is important to respect common general principles for the cross-border laboratory report exchange:

- Laboratory tests should be precisely and unambiguously specified.
- Laboratory result should include information about specimen type or the investigated system, analyte (component), the test method (measurement principle), the property of measurement, the timing (e.g., point in time, period of sample collection, if relevant), and measurement unit.
- The units must be scalable – use of derived units which can always be represented as products of powers of the base units must be possible.
- It should be possible to group and aggregate codes on a higher granularity level (for example the same items regardless of the method) or for comparable measurements.
- The laboratory result should be interpreted (reference ranges should be provided).
- Laboratory report recipients should be able to see the report in their preferred form regarding grouping of test results, using friendly test names and units, etc.

Article 11: Terminology

1. As the laboratory practice was one of the first areas in healthcare that was supported by information systems, several international standard test coding systems have been developed over the years – like Nomenclature for Properties and Units (NPU), Logical Observation Identifiers Names and Codes (LOINC), or SNOMED Clinical Terms (SNOMED CT), to name the main ones. Many other national or local code systems exist across Europe.
2. According to a survey performed in 2019 during preparation of a Common Semantic Strategy paper, two main international laboratory terminology systems for test coding are being used: Logical Observation Identifiers Names and Codes (LOINC) and Nomenclature for Properties and Units (NPU). In addition, there is variation within and between Member States of coding of laboratory tests even when the same terminology system is used. EU member states with well-established electronic laboratory communication will likely not change their existing laboratory coding practices thus transcoding to the selected pivot terminology or acceptance of more than one code

system represents one of the main challenges on the way to the semantic interoperability of laboratory result cross-border communication.

Logical Observation Identifier Names and Codes (LOINC)

Many laboratories use electronic message standards to transmit results to their clients. If all laboratories used the same "universal" set of test identifiers, electronic transmission of results would be greatly simplified. The Logical Observation Identifier Names and Codes (LOINC) database aims to be such a code system, covering at least 98% of the average laboratory's tests.

There are six axes or major elements, called **LOINC Parts**, which comprise the **LOINC Terms** semantic structure: component, property, timing, system, scale, and method.

The LOINC system is maintained and developed by Regenstrief Institute, Minneapolis, US and funded by National Library of Medicine, among others. To help guide the overall LOINC development, Regenstrief organized the LOINC Committees. The terms are translated and available in several European languages.

More information about LOINC terminology could be found at https://loinc.org website. LOINC codes could be searched online at https://loinc.org/search (free after registration).

Nomenclature for Properties and Units (NPU)

The NPU terminology is a patient-centred clinical laboratory terminology used for clinical laboratory sciences. The joint committee for nomenclature, C-NPU, under the two international organisations IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and IUPAC (International Union of Pure and Applied Chemistry) is responsible for the scientific development of the NPU terminology according to strict metrological principles and international scientific recommendations in terminology. The International Release Centre, at the Danish eHealth Authority in Copenhagen, Denmark, is responsible for maintenance and publication of the English version of the terminology. New codes and concepts are created after suggestions by users under the condition that the descriptions of the concept fulfils the metrological principles.

The NPU concept model identifies examined properties of a patient, independent of the technology or procedure used to obtain the information. The NPU definition encompasses essential information about an examination result in a formal structure, identifying the part of the universe that is studied (the system), the component examined in that system, the estimated kind-of-property of the component in that system, and the SI measurement unit where relevant.

More information about the NPU terminology can be found at http://npu-terminology.org.

SNOMED CT

In particular, complementary to the coding of laboratory tests, test results are to be documented in a standardised and coded way too. Regularly, test results are expressed via SNOMED CT concepts. As SNOMED CT is the most extensive terminology in health care, this code system offers solutions for the coded representation of laboratory-related facts in most cases. SNOMED

CT is an international standard of multilingual clinical healthcare terminology, encompassing clinical findings, symptoms, diagnoses, procedures, body structures, organisms and other aetiologies, substances, pharmaceuticals, devices and specimens in computer processable format used in clinical documentation and reporting.

UCUM
Quantitatively measured results are documented by standardised units, which are expressed preferably via UCUM to allow computer processing.

Code system mapping
The different coding practices in use among and within members states, also within users of the same code system, is an obvious obstacle to sharing of laboratory result reports. To remedy the situation mapping between code systems have been proposed. Particularly, a mapping between LOINC and NPU terminologies could allow for querying for laboratory results across terminology borders as well as for presenting and organising cross-border results in a similar manner as local or national laboratory results. The feasibility of such a mapping has been initially explored by the X-eHealth project. While mapping of the full code systems might be unrealistic, mapping of a subset of frequent and/or critical laboratory observations could be feasible. It is assumed that such mapping work would require resources, including domain experts, for development followed by support for long-term maintenance. Collaborative work between LOINC owners and SNOMED International, currently on hold, have produced a map between LOINC and SNOMED CT (approx. 20 000 LOINC terms) and could serve as proof-of-concept for future work.

Article 12: Controlled Lists (Value set Catalogue)

There is no specific support information.

Chapter V - Technical Considerations

Article 13: Technical requirements

There is no specific support information.

Article 14: Security

There is no specific support information.

Article 15: Testing and audit

There is no specific support information.

4 LABORATORY RESULT DATASET

The datasets indicated in the following tables are considered relevant for patient safety and the provision of adequate level of care both at cross-border and national level.

It is up to each implementation project to decide on the conformity and cardinality (i.e. data elements required or optional and number of repetitions), unless specifically stated.

Implementation projects need to make a final decision on mandatory and/or required (null allowed) elements.

4.1 Report header

Field		Field description	Preferred Code System
A.1 Report header data elements			
A.1.1 Identification of the patient/subject			
A.1.1.1	Family name/surname	The family name/surname/last name of the patient. This field can contain more than one element or multiple fields could be present.	
A.1.1.2	Given name	The given name/first name of the patient (also known as forename or first name). This field can contain more than one element.	
A.1.1.3	Date of birth	The date of birth of the patient [ISO TS 22220]. As age of the patient might be important for correct interpretation of the test result values, complete date of birth should be provided.	Complete date, without time, following the ISO 8601
A.1.1.4	Personal identifier	An identifier of the patient that is unique within a defined scope. Example: National ID (birth number) for Czech patient. Multiple identifiers could be provided.	

Field		Field description	Preferred Code System
A.1.1.5	Gender	This field must contain a recognised valid value for "administrative gender". If different, "physiological gender" should be communicated elsewhere.	HL7 Administrative Gender
A.1.2 Patient/subject related contact information			
A.1.2.1	Address	Mailing and home or office addresses. The addresses are always sequences of address parts (e.g. street address line, country, ZIP code, city) even if postal address formats may vary depending on the country. An address may or may not include a specific use code; if this attribute is not present it is assumed to be the default address useful for any purpose.	ISO 3166
A.1.2.2	Telecom	Telecommunication contact information (addresses) associated to a person. Multiple telecommunication addresses might be provided.	
A.1.3 Health insurance and payment information			
A.1.3.1	Health insurance information	Health insurance information is not always required, however, in some jurisdictions, the insurance number is also used as the patient identifier. It is necessary not just for identification but also forms access to funding for care.	
A.1.3.1.1	Health insurance code	Unique health insurance company identification code.	
A.1.3.1.2	Health insurance name	Full, official name of the healthcare insurance provider.	
A.1.3.1.3	Health insurance number	Number or code under which the insured person is registered at the insurance provider.	

Field		Field description	Preferred Code System
A.1.4 Information recipient (intended recipient or recipients of the report, additional recipients might be identified by the ordering party, e.g. GP, other specialist), if applicable			
A.1.4.1	Recipient identifier	The health professional identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number. In case when recipient is not a health professional, e.g. patient, appropriate personal identifier should be used.	
A.1.4.2	Recipient name	Person name.	
A.1.4.3	Recipient organization	The healthcare provider organization information.	
A.1.5 Author (by whom the Laboratory result report or a subset of its results was authored)			
A.1.5.1	Author identifier	The health professional or authoring device identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number.	
A.1.5.2	Author name	Person or device name.	
A.1.5.3	Author organization	The healthcare provider organization information.	
A.1.6 Legal authenticator (The person taking responsibility for the medical content of the document)			
A.1.6.1	Legal authenticator identifier	The health professional identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number.	

	Field	Field description	Preferred Code System
A.1.6.2	Legal authenticator name	Person name.	
A.1.6.3	Legal authenticator organization	The healthcare provider organization information.	
A.1.6.4	Authentication date and time	Date and time when the document was authorized.	ISO 8601
A.1.7 Result validator			
A.1.7.1	Result validator identifier	The health professional identification number. Either an internal identifier assign by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number.	
A.1.7.2	Result validator name	Person name.	
A.1.7.3	Result validator organisation	The healthcare provider organisation information.	
A.1.7.4	Validation date and time	Date and time when the document was validated.	ISO 8601
A.1.8 Laboratory report metadata			
A.1.8.1	Document type	A coded type of the document. Fixed value "Laboratory report"	LOINC
A.1.8.2	Document status	The status of the laboratory test result report. E.g., preliminary, final.	hl7:DiagnosticReportStatus
A.1.8.3	Report date and time	Date and time of the result report creation.	ISO 8601
A.1.8.4	Document title	Document title, e.g. "Laboratory Result report"	
A.1.8.5	Report custodian	Organisation that is in charge of maintaining the laboratory report	

4.2 Report body

Field		Field description	Preferred Code System
A.2 Order information (Laboratory Result Report could respond to multiple test orders)			
A.2.1	Order Id	An identifier of the laboratory test order. Laboratory Result Report may respond to multiple orders.	
A.2.2	Order date and time	Date and time of the order placement.	ISO 8601
A.2.3	Order placer identifier	The health professional identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number. In case when order placer is not a health professional, e.g. by patients themselves where applicable, appropriate personal identifier should be used.	
A.2.4	Order placer name	Person name.	
A.2.5	Order placer contact details	Contact details of order placer (address and telecom details).	
A.2.6	Order placer organization	Order placer organization information.	
A.3 Order reason (Laboratory Result Report could respond to multiple reasons)			

	Field	Field description	Preferred Code System
A.3.1	Problem / diagnosis / condition description	Health conditions affecting the health of the patient and are important to be known for a health professional during a health encounter. Clinical conditions of the subject relevant for the results interpretation.	ICD-10 (ICD-11 when available) SNOMED CT Orphacode
A.4 Specimen information			
A.4.1	Specimen identifier	An identifier of the specimen which is unique within in a defined scope. Example: identifier assigned by ordering system, identifier assigned by laboratory etc. Multiple identifiers can be used.	
A.4.2	Type of species	Biologic type of species for laboratory result reports bound to non-human subjects.	SNOMED CT
A.4.3	Material	Specimen material.	SNOMED CT
A.4.4	Collection period	Collection date time or period.	ISO 8601
A.4.5	Anatomic location	Anatomic location (body location, laterality) where the material is collected, e.g. Elbow, left	SNOMED CT
A.4.6	Morphology	Morphological abnormalities of the anatomical location where the material is taken, for example wound, ulcer.	SNOMED CT
A.4.7	Source Device	If the material is not collected directly from the patient but comes from a patient-related object, e.g. a catheter	SNOMED CT EMDN
A.4.8	Collection procedure/method	If relevant for the results, the method of obtaining the specimen.	SNOMED CT
A.4.9	Received date	Date and time that the material is handed over at the laboratory or specimen collection centre.	ISO 8601

Field		Field description	Preferred Code System
A.5 Results data elements			
A.5.1 Laboratory report narrative			
A.5.1.1	Narrative report	Entire report (textual summary inside the laboratory result report document) as issued by the laboratory.	
A.5.1.2	Comments, interpretation and recommendations	Comments, such as a textual interpretation or advice accompanying the result report, for example.	
A.5.2 Observation details (report could consist of multiple observations)			
A.5.2.1	Observation date	Date and time of the observation	ISO 8601
A.5.2.3	Observation code	Code representing the observation using the agreed code systems.	LOINC NPU SNOMED CT
A.5.2.3.1	Observation name	Full name of the observation according to the used test coding standard.	
A.5.2.3.2	Observation original name	Original (conventional) name of the observation as used by the laboratory	
A.5.2.3.3	Observation display name	Simplified (short name of the observation) for display.	
A.5.2.4	Observation method	Observation method (measurement principle) to obtain the result.	SNOMED CT
A.5.2.5	Observation device	Device (analyser), laboratory test kit and used calibrator information (identifier, type, name, model, manufacturer)	SNOMED CT EMDN
A.5.2.8	Order	Identifies order and order placer this observation belongs to.	

	Field	Field description	Preferred Code System
A.5.2.9	Performer	Identifies the originator/author and provides provenance information about the source of the results data that may have not originated with the source of the whole Laboratory Report document.	
A.5.2.10	Reporter	With certain observation results, e.g. there may also be an interpreter or a person responsible for validation.	
A.5.2.11	Observation result	Result of the observation including text, numeric and coded results of the measurement and measurement uncertainty. Content of the observation result will vary according to the type of the observation.	SNOMED CT (for ordinal or nominal scale results and result interpretation) UCUM (for units)
A.5.2.12	Observation interpretation	Information about reference intervals and result interpretation.	SNOMED CT HL7 v3 Code System ObservationInterpretation
A.5.2.13	Result description	Comments and narrative representation of the observation result and findings.	
A.5.2.14	Accreditation status	Accreditation status of the laboratory for the particular observation.	

5 REFERENCES AND EXAMPLES

ISO 15189 - https://www.iso.org/standard/56115.html

IHE XD-LAB - https://wiki.ihe.net/index.php/Sharing_Laboratory_Reports